

201-15325

Anh Nguyen

06/02/2004 12:16 PM

To: NCIC HPV@EPA

cc:

Subject: Fw: Environmental Defense comments on the Fatty Nitrogen Derived Amines Category (revised category)

----- Forwarded by Anh Nguyen/DC/USEPA/US on 06/02/2004 12:15 PM -----



rdenison@environmentaldefense.org

06/02/2004 11:07 AM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, Karen Boswell/DC/USEPA/US@EPA, Miriam_Azimi-Osman@americanchemistry.com

cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on the Fatty Nitrogen Derived Amines Category (revised category)

(Submitted via Internet 6/2/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Miriam_Azimi-Osman@americanchemistry.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Fatty Nitrogen Derived Amines Category .

The Fatty Nitrogen Derivatives Panel of the American Chemistry Council, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data for the Fatty Nitrogen Derived (FND) Amines Category. This chemical category is composed of twenty-three chemicals subdivided into four subcategories.

The Introduction to the test plan briefly mentions that these chemicals are used primarily in the production of commercial surfactants and in a number of commercial processes. Little other background information is provided. No information is provided regarding their transport or other end uses. No information is provided regarding specific products in which they are used, their potential for release from these products, potential for human and environmental exposure as a result of their intended uses or as byproducts of their use, e.g., in wastewater, etc. While not strictly required, such information is useful in increasing understanding of the potential for health and environmental effects to occur; see below.

Our review of this submission indicates that each of the twenty-three chemicals in the FND amines category share very similar properties. Further, they share most of these properties with other surfactants that are suggested as sources of read across or bridged data to address the SIDS elements required by EPA's HPV Challenge; thus, it is appropriate that they be considered a chemical category.

A summary describing available data on these chemicals is presented in a well-organized and well-written test plan that is supported by numerous references and further summarized in a series of tables. Each of the referenced studies is described in considerably more detail in the extensive (667-page) robust summary. Our review of the robust summary indicates it too is well-organized and very thorough. Many of the studies are recent and were conducted under GLP. The older studies appear to have been carefully designed and conducted.

RECEIVED
OPPT/DC/US
JUN 03 2004

Data described in the robust summaries and summarized in the test plan indicate most chemicals in the FND amines category are degraded in the environment; however, a few are only very slowly degraded. All tested FND amines have low acute toxicity, are not mutagenic and do not have reproductive or developmental toxicity at doses that are not toxic to the dams. However, available or bridged data indicate they do have significant aquatic and repeated dose toxicity, and that they are dermal irritants. These potentially adverse effects can most probably be attributed to the surfactant properties of these molecules. Their low acute toxicity may well be attributable to the fact that they have limited water solubility, so that most of an oral or dermal dose may not have been absorbed. This speculation is supported by the reports of significant toxicity when these chemicals are administered repeatedly at relatively low doses. Dermal irritation resulting from contact of significant concentrations of these chemicals is likely to be limited to occupational exposures, but measures to prevent such exposures by adherence to appropriate industrial hygiene practices are not described. It is also apparent that aquatic toxicity and/or repeated dose toxicity could result from long-term, low-level release of these chemicals, but the significance of such a scenario is not discussed.

In summary, we are aware that ? in contrast to most chemicals considered in these HPV reviews ? surfactants exert both their intended use effects and their biological effects through their physical rather than their chemical properties. Thus, many of the required SIDS elements do not characterize the potential for adverse effects from these chemicals as well as they do for most other chemicals considered under this initiative. Therefore, we agree that additional studies are not necessary even though there are no data for FND amines in subcategory IV.

However, whereas we compliment the sponsor on the compilation and review of an extensive amount of material on chemicals in this category, we think this submission would be far more useful, given the potential toxicity of FND amines to aquatic organisms, and to mammals on repeated exposure, were it to provide a more thorough description of the potential for human and environmental exposure as a result of their production and use.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense